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Date: June 1, 2004

By

Mary Sims

Signature of person depositing U.S. Mail



**IN THE UNITED STATES PATENT  
AND TRADEMARK OFFICE**

**PATENT**

Applicant(s): Tim Clarot, et al.

Docket No.: 33205.0800

Serial No.: 10/663,010

Examiner: TBA

Filed: September 15, 2003

Group Art Unit: 1616

Title: METHOD AND COMPOSITION FOR  
DELIVERING ZINC TO THE NASAL  
MEMBRANE

Confirmation No.: 1757

**INFORMATION DISCLOSURE STATEMENT  
PURSUANT TO 37 C.F.R. §§1.97-1.98**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

Dear Commissioner:

In accordance with the duty of disclosure under 37 C.F.R. §1.56 and pursuant to 37 C.F.R. §§1.97-1.98, the references listed and identified on the attached Form PTO/SB/08a (substitute for Form 1449A/PTO) are being submitted herewith for consideration by the Examiner. Applicant understands the Office has waived the requirement under 37 CFR 1.98 (a)(2)(i) for submitting a copy of each cited U.S. patent and each U.S. patent application publication for all U.S. national patent applications filed after June 30, 2003. The filing date of this application is September 15, 2003; therefore, copies of the U.S. patents and published applications are not enclosed herewith; however, copies of the foreign patents and publications are enclosed.

The references are being cited only in the interest of candor and without any admission that they constitute statutory prior art or contain matters which anticipate the invention or which would render the same obvious, either singly or in combination, to a person of ordinary skill in the art.

For each item listed on the enclosed copy of Form PTO/SB/08a that is not in the English language, an English language translation of that item or a portion thereof or a concise explanation of the relevance of that item is set forth below:

German Patent No. DE2839793 relates to anti-inflammatory, analgesic and anti-pruritic compositions for topical application made by mixing an aqueous alcoholic solution of methanol or camphor with sufficient water soluble carboxyvinyl polymer to give a viscosity of 2,000 to 20,000 centipoises at 20 DEG C., sufficient basic agent, such as an amine, to neutralize the carboxyl groups to a pH of 6.0-7.5 and a small amount of sodium chloride.

Japan Patent No. JP61068413 relates to a gel composition for external use that is obtained by using as a gelling agent, a combination of carboxyvinyl polymer with a hydroxyethylcellulose of a specific viscosity in specific amounts to inhibit the gel from being twisted and having improved feeling on use.

Japan Patent No. JP5124955 relates to obtaining a spraying gel base excellent in spreadability by disintegrating an agar jelly by mechanical stimulation.

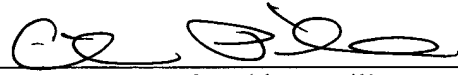
International Publication No. WO 00/78297 A2 relates to a biologically and chemically stable xylometazoline and/or oxymetazoline solution, containing glycerol and/or sorbitol and adjuvants.

This Information Disclosure Statement (IDS) is being filed under 37 C.F.R. §1.97(b) prior to the mailing date of the first office action. Therefore, no fee is due under 37 C.F.R. §1.17(p) since this Information Disclosure Statement is being filed in compliance with 37 C.F.R. §1.97(b)(1). If the Applicant has overlooked any fees, the Commissioner is hereby authorized to debit Deposit Account No. 19-2814 for the same. **A duplicate copy of this page of the Information Disclosure Statement is enclosed for this purpose.**

If there are any questions concerning this IDS, the Examiner is requested to contact the undersigned. If it is determined that this IDS has been filed under the wrong rule, the United States Patent and Trademark Office is requested to consider this IDS under the proper rule (with a petition if necessary) and charge the appropriate fee to Deposit Account No. 19-2814.

Respectfully submitted,

Dated: May 28, 2004

By:   
Cynthia L. Pillote  
Reg. No. 42,999

Enclosures: PTO/SB/08a  
Copies of 39 citations

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Substitute for form 1449A/PTO

Complete if Known

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 3

Application Number 10/663,010  
 Filing Date September 15, 2003  
 First Named Inventor Tim Clarot  
 Art Unit 1616  
 Examiner Name TBA  
 Attorney Docket Number 33205.0800

## U.S. PATENT DOCUMENTS

Examiner Initials <sup>*</sup>	Cite No. <sup>1</sup>	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
	A	US- 2,115,848		05-03-1938	Stanco Incorporated	
	B	US- 4,724,231		02-09-1988	Nastech Pharmaceutical, Inc.	
	C	US- 4,883,660		11-28-1989	Thames Pharmacal Co., Inc.	
	D	US- 4,970,240		11-13-1990	Schering Corporation	
	E	US- 5,114,979		05-19-1992	Schering Corporation	
	F	US- 5,158,761		10-27-1992	Toko Yakuhin Kogyo KK	
	G	US- 5,215,739		06-01-1993	Toko Yakuhin Kogyo KK	
	H	US- 5,240,694		08-31-1993	University of Virginia, et al.	
	I	US- 5,248,501		09-28-1993	Parnell Pharmaceuticals	
	J	US- 5,271,943		12-21-1993	Scott Health Care	
	K	US- 5,346,703		09-13-1994	Mediventures, Inc.	
	L	US- 5,478,565		12-26-1995	Warner-Lambert Company	
	M	US- 5,492,937		02-20-1996	Pharmacia AB	
	N	US- 5,760,085		06-02-1998	The Procter & Gamble Company	
	O	US- 5,785,988		07-28-1998	Fust	
	P	US- 5,854,269		12-29-1998	Schering-Plough Healthcare, etc.	
	Q	US- 5,897,858		04-27-1999	Schering-Plough Healthcare, etc.	
	R	US- 5,908,619		06-01-1999	Minnesota Mining and Mfg. Co.	
	S	US- 5,948,414		09-07-1999	Nouveau Technologies, Inc.	
	T	US- 5,988,870		11-23-1999	Partsky	

## FOREIGN PATENT DOCUMENTS

Examiner Initials <sup>*</sup>	Cite No. <sup>1</sup>	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind <sup>5</sup> (if known)				
	MM	DE	2839793	A1	05-10-1979	Toko Yakuhin Kogyo KK		
	NN	EP	0 147 476	A1	07-10-1985	Toko Yakuhin Kogyo KK		
	OO	JP	61068413	A2	04-08-1986	Lion Corp.		
	PP	EP	0 275 054	A1	07-20-1988	Toko Yakuhin Kogyo KK		
	QQ	EP	0 391 342	A1	10-10-1990	Toko Yakuhin Kogyo KK		
	RR	JP	5124955	A2	05-21-1993	Shiseido Co. Ltd.		
	SS	WO	94/00108	A1	01-06-1994	The Procter & Gamble Co.		
	TT	WO	94/05330	A1	03-17-1994	The Procter & Gamble Co.		
	UU	WO	99/38492	A1	08-05-1999	Novartis Consumer Health		
	VV	WO	00/10530	A1	03-02-2000	The Procter & Gamble Co.		

Examiner  
Signature

Date  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(use as many sheets as necessary)</i>			<b>Complete if Known</b>	
	Application Number	10/663,010		
	Filing Date	September 15, 2003		
	First Named Inventor	Tim Clarot		
	Art Unit	1616		
	Examiner Name	TBA		
Sheet	2	of	3	Attorney Docket Number
				33205.0800

U.S. PATENT DOCUMENTS						
Examiner Initials <sup>*</sup>	Cite No. <sup>1</sup>	Document Number		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> <i>(if known)</i>			
	U	US- 6,080,783		06-27-2000	Gum Tech International, Inc.	
	V	US- 6,090,403		07-18-2000	LecTec Corporation	
	W	US- 6,143,329		11-07-2000	Rorer Pharmaceutical Products	
	X	US- 6,235,312	B1	05-22-2001	Eastman Chemical Company	
	Y	US- 6,316,483	B1	11-13-2001	Schering Corporation	
	Z	US- 6,375,984	B1	04-23-2002	Rorer Pharmaceuticals Products	
	AA	US- 6,391,294	B1	05-21-2002	Reckitt Benckiser Healthcare	
	BB	US- 2001/0044411	A1	11-22-2001	Gelber, et al.	
	CC	US- 2001/0053775	A1	12-20-2001	Seidel, et al.	
	DD	US- 2002/0006961	A1	01-17-2002	Katz, et al.	
	EE	US- 2002/0012688	A1	01-31-2002	Dohi, et al.	
	FF	US- 2002/0022052	A1	02-21-2002	Dransfield	
	GG	US- 2002/0037297	A1	03-28-2002	Crespo, et al.	
	HH	US- 2002/0128273	A1	09-12-2002	Gelber, et al.	
	II	US- 2002/0172644	A1	11-21-2002	Haslwanter, et al.	
	JJ	US- 2002/0193417	A1	12-19-2002	Seidel, et al.	
	KK	US- 2002/0197212	A1	12-26-2002	Osbakken, et al.	
	LL	US- 2003/0031631	A1	02-13-2003	Osbakken, et al.	
		US-				
		US-				

FOREIGN PATENT DOCUMENTS								
Examiner Initials <sup>*</sup>	Cite No. <sup>1</sup>	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind <sup>5</sup> <i>(if known)</i>				
	WW	WO	00/78297	A2	12-28-2000	Boehringer Ingelheim Int'l		

Examiner Signature _____	Date Considered _____
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. Applicant is to place a check mark here if English language Translation is attached.

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			Application Number	10/663,010	
			Filing Date	September 15, 2003	
			First Named Inventor	Tim Clarot	
			Art Unit	1616	
			Examiner Name	TBA	
Sheet	3	of	3	Attorney Docket Number	33205.0800

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	XX	Abstract: ABD EL-BARY, A., et al.; "Bioavailability of Glibenclamide From Nasal Delivery Systems"; Pharmazeutische Industrie (1991), 53 (12), pgs. 1151-55	
	YY	Abstract: WASICKO, M.J., et al.; "The Role of Vascular Tone in the Control of Upper Airway Collapsibility"; American Review of Respiratory Disease (June 1990), 141 (6), pgs. 1569-77	
	ZZ	Abstract: KUMAR, V., et al.; "Aqueous vs Viscous Phenylephrine"; Archives of Ophthalmology (August 1986), 104 (8), pgs. 1189-91	

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

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